

REMARKS

Claims 1-3, 7-19, and 21 are pending in this application. Claims 3 and 7-19 have been withdrawn. Claims 4-6 and 20 have been canceled. Claims 1 and 2 have been amended in order to overcome rejections under 35 U.S.C. §112 and to correct the names of compounds (vi) and (vii). Claim 20 has been canceled, and replaced by new claim 21. Although claims 3 and 7-19 have been withdrawn, they are subject to Applicants' request for rejoinder.

The amendments do not introduce new matter within the meaning of 35 U.S.C. §132. Basis for the claim amendments is found on pages 3-7; in claims 1-19 as originally filed; and elsewhere throughout the specification and claims. Accordingly, entry of the amendments is respectfully requested, prior to any action being taken in relation to the Notice of Appeal filed concurrently with this Response.

Applicants would like to thank the Examiner for the withdrawal of the rejections under 35 U.S.C. §102(a), (b), and (e).

1. Restriction

Applicants have previously requested rejoinder of claims 7-19, directed to a process for making the inventive compounds, which have the same limitations as, or are dependent from, the compound claims as ultimately allowed, under the **mandatory** rejoinder

provisions of MPEP §821.04. Applicants respectfully request that the Examiner notify Applicants of the scope of allowed compound claims prior to issuance of a Notice of Allowance, so that appropriate amendments, if any are necessary, may be entered for the process claims. Applicants respectfully submit that rejoinder under MPEP §821.04 is mandatory regardless of whether the election of an inventive group was with or without traverse. Applicants have consistently asserted the right to rejoinder under MPEP §821.04 throughout the prosecution of this application.

**2. Rejection of Claim 1 under 35 U.S.C. §112,
first paragraph**

The Office Action rejects claim 1 under 35 U.S.C. §112, first paragraph, for the following reasons:

No support in the instant specification or the originally filed claims can be found for R representing 2-propenyl as claimed in instant claim 1. Applicants did not show where support in the specification or the originally filed claims could be found {page number(s) and line number(s)} for R representing 2-propenyl. Applicants should specifically point out the support for any amendments. See M.P.E.P. §§ 714.02 and 2163.06. Further, enablement for a single compound cannot provide enablement for the breadth of claims sought in arts which are unpredictable. Ex parte Hitzemann,, 9 USPQ2d 1821 (BPAI 1987).

RESPONSE

In order to advance prosecution, Claims 1 and 2 have been amended, and new claim 21 has been added, to remove 2-propenyl as

a substituent for variable R in claim 1, to remove compound (viii) as a species in the Markush group in claim 2, and to provide a separate, independent claim for compound (viii). These amendments obviate the outstanding rejection, and are expected to overcome any possible rejection relating to the proper dependency of a claim to compound (viii).

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 1 under 35 U.S.C. §112, first paragraph. It was agreed during the interview that if the amendments to claims 1 and 2 overcame their respective rejections, that the Examiner would enter the amendments, at least for purposes of appeal.

**3. Rejection of Claim 2 under 35 U.S.C. §112,
second paragraph**

The Office Action rejects claim 2 under 35 U.S.C. §112, second paragraph, for the following reasons:

In claim 2, compounds (i) and (v) lack antecedent basis from claim 1 since in claim 1, the R variable represents a C₂ to C₅ alkyl chain.

RESPONSE

In order to advance prosecution compounds (i) and (v) have been removed from claim 2, without prejudice or disclaimer of the subject matter therein.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 2 under 35 U.S.C. §112, second paragraph.

4. Rejection of Claims 1, 2, and 20 under 35 U.S.C. §103(a)

The Office Action rejects claims 1, 2, and 20 under 35 U.S.C. §103(a) as being unpatentable over Raman et al. (U.S. Pat. 6,346,539). As the basis for this rejection, the Office Action cites MPEP §§2141.01, 2141.02, and 2142-2413, and states:

Determination of the scope and content of the prior art (MPEP §2141.01). Applicants claim arylalkenoic acid heterocyclic amide compounds. Raman et al. teach arylalkenoic acid heterocyclic amide compounds that are structurally similar to the instant claimed compounds (column 3, lines 1-40; and the "alterations to nitrogen substituent" and "alterations to the phenyl substituent" in columns 5-6). See in Raman et al., for example, the compounds of formula (i) at the top of column 3 wherein n is zero; R2 and R3 together represent a carbon to carbon double bond; R1 is an alkoxy group having from 1 to 3 carbon atoms; m is one and R6 represents a morpholino group (also see Applicants' compound vi in instant claim 2).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02). The difference between the compounds in the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413). The indiscriminate selection of "some" among "many" is prima facie obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating skin conditions).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, skin conditions. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

* * *

Presently, only compounds are under examination in the instant application. There is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990).

Further, Raman et al. do direct one skilled in the art toward Applicants' specie found in instant claim 2. See in Raman et al. the compounds of formula (i) at the top of column 3 wherein n is zero, R2 and R3 together represent a carbon to carbon double bond; R1 is an alkoxy group having from 1 to 3 carbon atoms; m is one and R6 represents a morpholino group (also see Applicants' compound vi in instant claim 2). Further note the section titled "alterations to nitrogen substituent" and "alterations to the phenyl substituent" in columns 5-6 in Raman et al. Absent unexpected, unobvious and beneficial results of the instant claimed compounds over the compounds taught in Raman et al., the instant claimed compounds would have been suggested to one skilled in the art and therefore, would have been obvious to one skilled in the art.

RESPONSE

Applicants respectfully traverse this rejection on the basis that the generic disclosure in the cited reference fails to teach or suggest the specific subgenus and species compounds claimed

herein. The Office Action thus fails to establish a *prima facie* case of obviousness.

Applicants claim a genus of substituted aryl alkenoic acid heterocyclic amides, which are disclosed and claimed as having utility as spicy and pungent food additives. With the rejections under 35 U.S.C. §102 having been withdrawn, it is thus admitted that none of the cited references discloses a compound as presently claimed. As the Examiner candidly admits, the cited reference teaches use of the compounds disclosed therein for treating skin conditions.

Contrary to the Office Action, the Federal Circuit has repeatedly and consistently held that the fact that a claimed species or subgenus is encompassed by a prior art genus is **not** sufficient by itself to establish a *prima facie* case of obviousness: "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious." (*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). Indeed, the Federal Circuit has held that: "we decline to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989) the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it." See also *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed.

Cir. 1992) and *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art reference must teach or suggest all the limitations of the claims. *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Third, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991).

To establish a *prima facie* case of obviousness in a genus-species chemical composition situation, as described in detail in MPEP §2144.08, the Examiner must find some motivation or suggestion to make the claimed invention in light of the prior art teachings: "[T]he mere possibility that one of the esters or the active methylene group-containing compounds... could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious 'unless the prior art suggested the

desirability of [such a] modification' or replacement." (*In re Brouwer*, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996), quoting *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). "[A] proper analysis under §103 requires, *inter alia*, consideration of... whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process." (*In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). In order to find such motivation or suggestion there should be a reasonable likelihood that the claimed invention would have the properties disclosed by the prior art teachings. Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness.

MPEP §2144.08 further provides that "[i]n the case of a prior art reference disclosing a genus, Office personnel should make findings as to:

(A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;

(B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;

(C) the predictability of the technology; and

(D) the number of species encompassed by the genus taking into consideration all of the variables possible."

This the Examiner has, apparently, failed to do; none of these factors are discussed in any Office Action to date. There is no evidence in the record of the predictability of the technology, and the Examiner admits that "...enablement for a single compound cannot provide enablement for the breadth of claims sought in arts which are **unpredictable**." (Emphasis added.)

The Examiner relies on two arguments: (1) that the instant claimed compounds are **generically** described in the prior art, and (2) that Applicants careful selection and testing of the claimed compounds is somehow an "indiscriminate" selection of some among many. In light of the proper considerations discussed above, the former is irrelevant, while the latter is factually inaccurate, unsupported by any evidence in the record, and was and is contradicted by Applicants.

The Prior Art Disclosed Structures are Different from the Claimed Compounds. Contrary to the Office action, Raman, et al. do not teach or suggest the inventive compounds. Aside from the generic disclosure found in column 3, the specific disclosure found from column 4, line 13 through column 5, line 53, including the Table at columns 5 and 6, the Examples, and the claims teach specific compounds which are different than the presently claimed compounds; in fact, Raman, et al. teaches away from the inventive compounds.

In particular, while the Examiner asserts that the "alterations to nitrogen substituent" and "alterations to the phenyl substituent" in columns 5-6 teach inventive compounds, it is apparent on a fair reading of those sections of Raman, et al. that the "alterations to nitrogen substituent" are made in relation to 1-(5-benzo-1,3-dioxol-5-yl-pentanoyl)-derivative compounds, which is not a presently claimed compound or derivative. Similarly, the "alterations to nitrogen substituent" are made in relation to a piperidino as the nitrogen substituent, while the inventive compounds require a morpholino or piperizino nitrogen substituent. In both instances, Raman, et al. do not teach the presently claimed compounds, teaching away instead.

The Prior Art Utilities are Different than the Utilities of the Claimed Compounds. As discussed in detail herein and in previous Responses, the disclosed utility in Raman, et al. is treating skin conditions, while the utility of the claimed compounds is as spicy and pungent food additives. Although the Examiner expressly stated that utility is irrelevant to an obviousness rejection during the telephone interview conducted on October 12, 2004, the authorities cited above and in MPEP §2144.08 make clear that different utilities are a factor supporting non-obviousness.

The Number of Species Encompassed by the Prior Art Genus Is Large. Raman, et al. has a minimum of four and a maximum of ten

variable R groups, depending on the selections of n and m. Applicants calculate that there are a minimum of 136,000 species encompassed by Raman, et al., and that there is no teaching whatsoever as to the selection among the large number of possible species, other than as specifically disclosed from column 4, line 13 through column 5, line 53, as described in the Examples, and as claimed therein.

Determination of the Differences Between the Closest Disclosed Prior Art Species or Subgenus of Record and the Claimed Species or Subgenus. The Office Action fails to make explicit findings on the similarities and differences between the closest disclosed prior art species or subgenus of record and the claimed species or subgenus, including findings relating to similarity of structure, chemical properties, and utilities. Indeed, the closest disclosed prior art species is not identified at all. Thus, there is a failure to establish a prima facie case of obviousness. Without waiving this deficiency, the specific compounds disclosed in Raman, et al. are structurally different than the presently claimed compounds, as discussed in greater detail above.

Lack of Motivation To Select the Claimed Species or Subgenus. "[A] prima facie case of unpatentability requires that the teachings of the prior art suggest the claimed compounds to a person of ordinary skill in the art." (*In re Jones*, 958 F.2d at 351, 21 USPQ2d at 1943-44 (Fed. Cir. 1992); see also *In re Dillon*,

919 F.2d at 692, 16 USPQ2d at 1901). "The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound." (*In re Lahu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984)). Ultimately, there must be evidence to support a conclusion that one of ordinary skill in the relevant art must have been motivated to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus. (*In re Ochiai*, 71 F.3d at 1569-70, 37 USPQ2d at 1131; *In re Deuel*, 51 F.3d at 1557, 34 USPQ2d at 1214; *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996)).

Some motivation to select the claimed species or subgenus must be taught by the prior art: "Absent anything in the cited prior art suggesting which of the 1036 possible sequences suggested by Rinderknecht corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences." (*In re Bell*, 991 F.2d at 784, 26 USPQ2d at 1531; see also *In re Deuel*, 51 F.3d at 1558-59, 34 USPQ2d at 1215; *In re Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552; and *In re Ruschig*, 343 F.2d 965, 974, 145 USPQ 274, 282 (CCPA 1965)).

The Examiner has cited no reference which teaches or suggests that compounds useful for treating skin conditions also are useful as spicy and pungent food additives. To the contrary, one of

ordinary skill in the art would almost certainly be discouraged from using spicy and pungent compounds for treating skin conditions, fearing skin irritation, and would be unlikely to consider using compounds useful in stimulating melanocyte proliferation as a food additive.

In the absence of any teaching or suggestion in the cited references that the prior art piperine compounds and derivatives, used for treating skin conditions, should, with a reasonable expectation of success apparent to one of ordinary skill in the art, be modified to produce the particular substituted aryl alkenoic acid heterocyclic amides useful as a spicy and pungent food additive, as claimed herein, the claims of the present application cannot be obvious over Raman et al. (U.S. Pat. 6,346,539). The Examiner has failed to establish a *prima facie* case of obviousness.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of remaining claims 1-3 and 7-19 and 21, to allow pending claims 1-2 and 21

presented herein for reconsideration, and to rejoin and allow claims 3 and 7-19. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

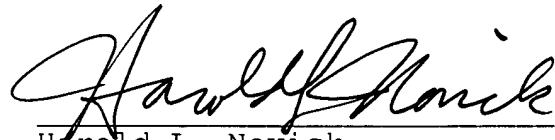
The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,

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